Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0870459	06/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Oncology Associates (Williamsburg)	500 Sentara Cirle - Suite 203, Williamsburg, VA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA validation survey was conducted at Virginia Oncology Associates on June 25, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, and an interview, the laboratory failed to rotate PT among personnel performing patient hematology testing for seven (7) of 7 events reviewed in calendar years 2019, 2020, and year to date 2021. Findings include: 1. Review of the CMS 209 revealed that the laboratory director identified 4 testing personnel (TP #1-4) responsible for complete blood count (CBC) hematology patient testing during the review timeframe of January 2019 to June 25, 2021. (See Personnel Code Sheet.) 2. Review of the laboratory's American Proficiency Institute (API) hematology PT records revealed that TP #1 and #2 signed attestations as performed the following six events: 2019 (Event 1, 3), 2020 (Events 1-3), 2021 (Event 1). The inspector noted no attestation for 2019 Event 2. The inspector requested attestation documentation for 2019 Event 2. No record was available for review (See D 2015). The inspector noted no attestations or PT rotation for TP #3 or #4 on the 7 events outlined above. 3. An interview with the general supervisor on 6/25 /21 at approximately 2 PM confirmed the above findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director and testing personnel for one (1) of seven (7) events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute 2019 (Event 1-3), 2020 (Events 1-3), 2021 (Event 1) hematology PT documentation, a total of 7 events, revealed no signed attestation statements for 2019 Event 2. The inspector requested to review the attestation documentation. No documentation was available for review. 2. An interview with the general supervisor on 6/25/21 at approximately 2 PM confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a tour, review of package insert, temperature logs, procedures, lack of documentation, and an interview, the laboratory failed to retain documentation of monitoring temperatures of the refrigerator, freezer, and laboratory room/ humidity to ensure proper storage of hematology reagents, quality control (QC) material, and storage of patient samples for the six (6) month review timeframe of January 2020 to July 2020. Findings include: 1. During a laboratory tour on 6/25/21 at approximately 10:30 AM, the inspector requested to review the manufacturer's package insert for the Sysmex hematology XN Check QC materials. The package insert stated under Storage and Shelf Life instructions: "Store 2-8 C. Avoid freezing this material. Storage outside of the recommended temperature range causes damage to the products. Do not use damaged materials for control verification." 2. Review of the laboratory's temperature logs for a twenty-four month period of June 2019 to the date of survey on 6/26/21 revealed no documentation of recording temperatures/humidity for the following months in calendar year 2020: January, February, March, April, May, and June. The inspector requested to review the 2020 temperature logs for the 6 months outlined

	above. No documentation was available for review. 3. Review of the laboratory's procedure manual revealed a quality assurance policy that outlined protocols to monitor the room temperature, refrigerator/freezer storage temperatures, and hematology room temperature/humidity daily. 4. An interview with the general supervisor on 6/25/21 at approximately 2 PM confirmed the above findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), analyzer installation validation records, manufacturer's users guide, laboratory personnel files, and an interview, the technical consultant (TC) failed to document training and competency evaluations for four (4) of 4 testing personnel (TP) after a hematology instrument change occurred in calendar year 2020. Findings include: 1. Review of the CMS 116 and 209 forms revealed that the lab director (LD) identified 4 TP as responsible for moderate complexity hematology analyzer operation for patient testing and that the LD also performed the duties of TC. 2. Review of hematology procedures revealed the laboratory changed from a Sysmex XT 4000 analyzer to a Sysmex XN 1000 for Complete Blood Count (CBC) testing in January 2020. 3. Review of the laboratory's instrument validation records revealed the Sysmex XN 1000 analyzer verification studies were approved on 01/07/20 by the LD. 4. Review of the Sysmex XN User's Guide revealed manufacturer's instructions that the "Sysmex XN 1000 Training Checklist is to be completed prior to patient testing". 5. Review of the laboratory personnel files and installation records revealed that TP #1, #2, #3, and #4 lacked a Sysmex XN Training Competency checklist and evaluation. The inspector requested to review the training competency evaluations. No documentation was available for review. (See Personnel Code Sheet.) 6. An interview with the general supervisor on 6/25/21 at approximately 2 PM confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files,

	and an interview, the technical supervisor (TS) failed to perform annual Hematology competency evaluation for one (1) of the three (3) testing personnel (TP) in calendar year 2020. Findings include: 1. Review of the CMS 116 and 209 forms revealed that the laboratory director identified 3 TP were responsible for high complexity hematology patient testing during the twenty-four months reviewed (June 2019 to June 25, 2021). 2. Review of the laboratory personnel files revealed that testing personnel A lacked a 2020 annual Hematology competency evaluation. (See Personnel Code Sheet) 3. An interview with the general supervisor on 6/25/21 at approximately 2 PM confirmed the above findings.